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10/682,278	10/08/2003	Syed Faiyaz Ahmed Hossainy	50623.342	9337

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EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	**PAPER NUMBER**
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	**Application No.** 10/682,278	**Applicant(s)** HOSSAINY, SYED FAIYAZ AHMED	
	Examiner Kathleen Sonnett	**Art Unit** 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *4/2/2004*.
4)☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 23, 27, 29, 33, 34, 36, 37, and 39** are rejected under 35 U.S.C. 102(e) as being anticipated by Ding et al. (U.S. 6,099,562). Ding et al. discloses a stent comprising a coating, the coating including a first layer made of a first polymer (103) and a discontinuous second layer (104) having a segment separated by the first layer, the second layer made of a second polymer (col. 4 ll. 50-58).

3. Regarding claim 27, the first layer contains a first active ingredient and the second layer contains a second active ingredient (col. 14 ll. 28-35).

4. Regarding claim 29, the release rate of the first active ingredient is different than the release rate of the second active ingredient since the drugs in the topcoat will elute first followed by the drugs (col. 14, ll. 28-35).

5. Regarding claim 33, the first and second polymers are different (col. 13 ll. 40-44; 56-58).

6. Regarding claim 34, Ding et al. discloses a stent comprising a substrate (101) and a polymeric coating formed on a region of the substrate wherein the polymeric coating includes alternating sections of a first and second layer along a length of a segment of the substrate. That is, following the outermost portion of the coating along a length of a segment of the

substrate, the polymeric coating will at times be the first layer and at times be the second layer due to the discontinuous application of the top layer of the coating.

7. Regarding claim 36, see col. 2 ll. 60+.

8. Regarding claims 37 and 39, see col. 14 ll. 28-35.

9. **Claims 34, 36-38, and 40** are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (U.S. 5,873,904). Ragheb et al. discloses a stent comprising a substrate (14) and a polymeric coating formed on a region of the substrate wherein the polymeric coating includes alternating sections of a first layer (18) and a second layer (20) along a length of a segment of the substrate. In particular, Ragheb et al. discloses a stent covered with a bioactive material layer (18). Ragheb et al. further discloses that a portion of this layer may be etched away allowing the porous polymeric layer 20 that is applied over layer 18 to directly connect to the base material (14) of the stent (col. 17 ll. 15-20). Layers 18 and 20 together form a polymeric coating.

10. Regarding claim 36, see col. 9 ll. 1-10.

11. Regarding claim 37, the first layer includes a first active ingredient and the second layer includes a second active ingredient. In particular, Ragheb et al. discloses that the second layer (20) may have a bioactive ingredient incorporated in it in order to improve biocompatibility (col. 16 ll. 41).

12. Regarding claim 38, Ragheb et al. further discloses applying additional layers that cover at least a portion of the first and second layers to reduce a rate of release of the active ingredients from other layers of the polymeric coating (col. 15 ll. 4-24).

13. Regarding claim 40, see col. 12 ll. 38-41.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. **Claims 23-28 and 30-31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuch (U.S. 5,824,048) in view of Ragheb et al. (U.S. 5,873,904). Tuch discloses a stent comprising a coating, the coating including a first layer made of a first polymer and a discontinuous second layer made of a second polymer (see abstract; col. 6 ll. 27-35 and 65-67). Tuch fails to disclose that the second layer has a segment separated by the first layer or that the first layer is also discontinuous having a segment separated by the second layer so as to create an alternating pattern of the first and second layer disposed on the surface of the stent.

16. However, Ragheb et al. discloses that it is old and well known in the art to have discontinuous first and second layers that have segments separated by the other layer so as to create an alternating pattern of first and second layers disposed on the surface of a stent. In particular, Ragheb et al. discloses a stent covered with a bioactive material layer (18). Ragheb et al. further discloses that a portion of this layer may be etched away allowing the porous layer 20 that is applied over layer 18 to directly connect to the base material (14) of the stent (col. 17 ll. 15-20). Ragheb et al. discloses that this connection between the actual base material of the stent and the outer layer (20) helps further secure the layers together, allows the bioactive material to be divided into several segments such that it can partition different bioactive agents into different regions, and provides structural integrity to the device once the bioactive layers have been released. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Tuch to etch away a portion of the undercoat such that, when the topcoat is applied over the undercoat, the topcoat can connect directly to the base material of the stent

where the undercoat has been etched away as made obvious by Ragheb et al. in order to further secure the layers to the stent.

17. Regarding claim 25, Ragheb et al. discloses using a primer layer (16) underneath at least a portion of the first and second layers (see col. 12 ll. 38-41).

18. Regarding claim 26, the first and second layers create an alternating pattern of the first and second layers disposed on the primer layer.

19. Regarding claim 27, Tuch discloses that both the first and second layer contain active ingredients (see abstract).

20. Regarding claim 28, Tuch fails to disclose a third layer covering at least a portion of the first and second layers to reduce a rate of release of the active ingredients from the coating. However, Ragheb et al. discloses that adding additional layers on top of other layers can reduce a rate of release of the active ingredients from the coating layers beneath the additional layers (col. 15 ll. 4-24). The active ingredients from the bottom two layers may also promote the rate of release of the active ingredients from the top layer. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Tuch to include a third layer covering at least a portion of the first and second layers to reduce a rate of release of the active ingredients as made obvious by Ragheb et al. in order to gain the advantage of better controlling the release rate.

21. Regarding claim 30, the stent is radially expandable (col. 8 ll. 27-36).

22. Regarding claim 31, the first or second layer contains a radiopaque substance (col. 5 ll. 4 of Ragheb et al.).

23. **Claim 32** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. or Ragheb et al. Ding et al. and Ragheb et al. disclose the invention substantially as stated above but fail to disclose that the alternating sections have a width of about 5 microns to about 500

microns. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the width of the alternating sections of about 5 to about 500 microns because Applicant has not disclosed that this particular width range provides an advantage, is used for a particular purpose, or solves a stated problem over sections with widths falling out of this range. One of ordinary skill in the art, furthermore, would have expected Ding et al.'s or Ragheb et al.'s invention and applicant's invention, to perform equally well with a spacing falling within the range of about 5 to about 500 microns or outside this range since no criticality is disclosed for this particular range. Therefore, it would have been a prima facie obvious to modify Ding et al. or Ragheb et al. to obtain the invention as specified in claim 32 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Ding et al. or Ragheb et al.

24. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the width of the alternating sections of about 5 to about 500 microns because Applicant has not disclosed that this particular width range provides an advantage, is used for a particular purpose, or solves a stated problem over sections with widths falling out of this range as discussed above. One of ordinary skill in the art, furthermore, would have expected Ragheb et al.'s invention and applicant's invention, to perform equally well with a spacing falling within the range of about 5 to about 500 microns or outside this range since no criticality is disclosed for this particular range. Therefore, it would have been a prima facie obvious to modify Ragheb et al. to obtain the invention as specified in claim 38 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Ragheb et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
12/23/2006

GLENN K. DAWSON
PRIMARY EXAMINER